4501-1004
PATENT


**IN THE U.S. PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re application of | Appeal No. _____ |
| Robert Bartlett ELLIOTT et al. | Conf. 8690 |
| Application No. 10/019,506 | Group 1654 |
| Filed May 10, 2002 | Examiner R. Winston |

PROPHYLACTIC DIETARY SUPPLEMENT BASED ON MILK

## APPEAL BRIEF

MAY IT PLEASE YOUR HONORS:

(I) **Real Party in Interest**

The real party in interest in this appeal is the assignee, The New Zealand Milk Institute Limited of Otahuhu, New Zealand.

(II) **Related Appeals and Interferences**

Appellants are unaware of any other appeal or interference that would directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(III) **Status of Claims**

Claims 28-32 and 37-45 are pending. The present appeal is taken from the rejection of all of the pending claims 28-32 and 37-45.

(IV) **Status of Amendments**

A final Office Action was issued on June 2, 2005. No amendments have been filed in the application since that date.

(V) **Summary of Claimed Subject Matter**

Independent claim 28 is directed to a dietary supplement comprising an immunomodulating component and a fortifying component. The immunomodulating component may be selected from β-casomorphin-9 and β-casein A2 (page 10, lines 30-35 and page 11, lines 13-18). The fortifying component may be selected from betaine, cobalamin, folic acid, pyridoxine, and pharmaceutically acceptable analogues thereof (page 13, lines 15-25).

Claims 32 and 41-45 are method claims, which recite methods of using the claimed dietary supplement.

(VI) **Grounds of Rejection to be Reviewed on Appeal**

Claims 28-32 and 37-45 stand rejected under 35 USC 103(a) as allgedly being unpatentable over YOSHIKAWA et al. in view of WAKAT and KALVINSH et al. SPIREAS.

(VII) **Arguments**

Appellants believe that the proposed combination of publications fails to teach the claimed invention. YOSHIKAWA et al. studies the enzymatic release of pro-β-casomorphin-9 and β-casomorphin-9 from bovine β-casein. In studying these compounds, YOSHIKAWA et al. teach that β-casomorphins from bovine β-casein A2 exhibit opioid and ACE inhibitor activities

(YOSHIKAWA et al., page 42). However, YOSHIKAWA et al. fail to disclose or suggest utilizing these compounds in a dietary supplement.

Rather, the Office Action cites to SPIREAS as teaching that ACE inhibitors are useful for the treatment of cardiovascular disorders. While SPIREAS does teach that ACE inhibitors can be used to treat cardiovascular disorders, SPIREAS also teaches that "it has been widely observed that ACE inhibitors are susceptible to breakdown, especially due to degradation and/or cyclization between the time of manufacture and the time of desired usage." (Column 1, lines 22-28). As a result, SPIREAS specifically teaches that enalapril maleate, quinapril hydrochloride and similar salts, should be used to provide stable formulations (column 2, lines 20-40). SPIREAS does not disclose nor suggest that the claimed immunomodulating components can be used in a stable formulation, or that it would even be desirable to include the compounds recited in the claimed invention as a dietary supplement. In fact, one skilled in the art would be lead away from the claimed invention in view of the teaching of SPIREAS in that the ACE inhibitors are susceptible to breakdown.

As to the WAKAT and KALVINSH et al. publications, appellants believe that these publications fail to remedy the deficiencies of YOSHIKAWA et al. and SPIREAS for reference purposes. WAKAT teaches a dietary supplement but does not

disclose or suggest that the recited immunomodulating components of β-casomorphin-9 and β-casein A2 would provide a desirable dietary supplement. While KALVINSH et al. teaches a hydroxyl radical scavenger, KALVINSH et al. does not disclose or suggest that β-casomorphin or that β-casein A2 would be desirable in a dietary supplement.

As a result, appellants respectfully submit that the proposed combination of references fails to disclose or suggest the claimed dietary supplement or methods of using the claimed supplement.

From the above discussion, it is believed to be apparent that the rejection on appeal does not merit affirmance by the Board, but rather, that the rejection should be reversed. Such action is accordingly respectfully requested.

Respectfully submitted,

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February 2, 2006

(VIII) **Claims Appendix**

1-27. (canceled)

28. (previously presented) A dietary supplement comprising:

- an immunomodulating component selected from the group consisting of β-casomorphin-9 and β-casein A2, and

- a fortifying component which is an effective amount of at least one compound capable, when consumed, of reducing plasma levels of homocyst(e)ine (tHcy) in a mammal, said compound being selected from the group comprising betaine, cobalamin, folic acid, pyridoxine, and pharmaceutically acceptable analogues thereof.

29. (previously presented) The dietary supplement as claimed in claim 28, wherein the immunomodulating component is derived from bovine milk.

30. (previously presented) The dietary supplement as claimed in claim 29, wherein the milk has a β-casein content which substantially excludes β-casein A1 and β-casein B.

31. (previously presented) The dietary supplement as claimed in claim 30, wherein the β-casein content of the milk is substantially comprised of β-casein A2.

32. (previously presented) A method for reducing the incidence in a population of at least one of the group comprising (a) type I diabetes, (b) type II diabetes, (c) cardiovascular disease, (d) cerebrovascular disease, (e) peripheral vascular

disease, (f) neural tube defects, and (g) degeneration of blood vessel walls, comprising supplying to the population a dietary supplement as claimed in claim 28.

33-36. (canceled)

37. (previously presented) The dietary supplement according to claim 28, wherein the fortifying component is folic acid.

38. (previously presented) The dietary supplement according to claim 28, wherein the fortifying component is cobalamin.

39. (previously presented) The dietary supplement according to claim 28, wherein the fortifying component is pyridoxine.

40. (previously presented) The dietary supplement according to claim 28, wherein the fortifying component is betaine.

41. (previously presented) A method for treating a subject in a population to reduce the risk of a disorder selected from the group consisting of a) type I diabetes, b) type II diabetes, c) cardiovascular disease, d) cerebrovascular disease, e) peripheral vascular disease, f) neural tube defects, and degeneration of blood vessel walls from occurring in said subject, comprising administering an effective amount of the supplement according to claim 28 to said subject.

42. (previously presented) A method for treating a subject in a population to reduce the risk of a disorder selected from the group consisting of a) type I diabetes, b) type II diabetes, c) cardiovascular disease, d) cerebrovascular disease, e) peripheral vascular disease, f) neural tube defects, and degeneration of blood vessel walls from occurring in said subject, comprising administering an effective amount of the supplement according to claim 37 to said subject.

43. (previously presented) A method for treating a subject in a population to reduce the risk of a disorder selected from the group consisting of a) type I diabetes, b) type II diabetes, c) cardiovascular disease, d) cerebrovascular disease, e) peripheral vascular disease, f) neural tube defects, and degeneration of blood vessel walls from occurring in said subject, comprising administering an effective amount of the supplement according to claim 38 to said subject.

44. (previously presented) A method for treating a subject in a population to reduce the risk of a disorder selected from the group consisting of a) type I diabetes, b) type II diabetes, c) cardiovascular disease, d) cerebrovascular disease, e) peripheral vascular disease, f) neural tube defects, and degeneration of blood vessel walls from occurring in said

subject, comprising administering an effective amount of the supplement according to claim 39 to said subject.

45. (previously presented) A method for treating a subject in a population to reduce the risk of a disorder selected from the group consisting of a) type I diabetes, b) type II diabetes, c) cardiovascular disease, d) cerebrovascular disease, e) peripheral vascular disease, f) neural tube defects, and degeneration of blood vessel walls from occurring in said subject, comprising administering an effective amount of the supplement according to claim 40 to said subject.

(IX) **Evidence Appendix**

None.

(X) **Related Proceedings Appendix**

None.